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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/736,535

12/17/2003

Michael G. Tal

TAL-001

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EXAMINER

NGUYEN, VI X

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/736,535	Applicant(s) TAL, MICHAEL G.	
	Examiner Victor X. Nguyen	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-20 and 23-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20 and 23-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the RCE filed on 2/11/2009.

Claims 17-20 and 23-33 are pending in this present application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-20 and 23-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **In claim 17**, the disclosure does not describe “consequently stimulating fibrosis of the vein at the treatment site, thereby permanently occluding the vein”. The only disclosure of “irreversible” is on page 1, paragraph 12 of applicant’s specification, lines 1-3, “Vascular fibrosis and obliteration only occurs in response to irreversible endothelial cellular destruction”. However, the specification does not appear to disclose “that consequently stimulating fibrosis of the vein at the treatment site, thereby permanently occluding the vein as is now claimed”.

Claim 25 is rejected 112 first paragraph as the specification is non-enabling for the vein has a size at the treatment site of 2-10mm and the specification fails to support for any of these values.

Claim Rejections - 35 USC § 103

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3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-19, 23-24 and 26-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over R.A. Williams et al (Vol. 119, No. 11, November 1984) in view of Evans et al US 20020188276.

Claims 17, 23, 26-27, and 30: R.A. Williams et al (please see the entire article) disclose a similar method which includes injecting sclerosant into the vein at the treatment site causing irreversible damage to the disrupted lining endothelium at the treatment site and consequently stimulating fibrosis of the vein at the treatment site, thereby permanently occluding the vein (Vol. 119, No. 11, November 1984, see second column, second paragraph, page 1284 “The complication of modern sclerotherapy are as follows: localized venous **thrombosis**..., and the forth paragraph “The sclerosant sodium tetradecyl sulfate has detergent qualities that produce **venous intimal damage**, which is followed by **thrombophlebitis**”). It is noted that thrombosis is defined “the formation or presence of a blood clot within a blood vessel”. Furthermore, thrombophlebitis is defined “inflammation of a vein with formation of a thrombus” as evidenced by “Merriam-Webster online dictionary”. Thus, **thrombosis** or **thrombophlebitis** would cause some degree of occluding the vein. Moreover, the degree of occlusion is not being claimed.

R.A. Williams et al do not disclose advancing an elongated intraluminal member through the vein to a treatment site in the vein; moving activating the intraluminal member against the vein's lining at the treatment site to disrupt the lining.

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Evans et al teach advancing an elongated intraluminal member 12 through the vein to a treatment site in the vein (col. 2, paragraph 12); moving the intraluminal member against the vein's lining at the treatment site to disrupt the lining (paragraph 76).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify R.A. Williams et al by advancing an elongated intraluminal member through the vein to a treatment site in the vein; moving activating the intraluminal member against the vein's lining at the treatment site as taught by Evans in order to enhance the effectiveness of disrupting the vessel wall (paragraph 76).

Claims 18 and 19: Evans teaches the step of scraping the intraluminal member against the vein's lining (paragraph 76), and wherein the intraluminal member comprises a hollow infusion wire 12, and the sclerosant is injected into the vein through the hollow infusion wire.

Claim 24: Evans teaches the intraluminal member 12 is advanced through a sheath 32, and the sclerosant is injected into the vein through an annular space between the intraluminal member and the sheath.

Claims 26-27: Evans teaches wherein scraping comprises rotating the intraluminal member 12 in the vein so that a portion of the intraluminal member engages the lining, and where the portion of the intraluminal member that engages the lining is sharpened (fig. 3).

Claims 28-29, and 31-33: Evans teaches the intralummal member curves at a distal end, and wherein the intraluminal member is simultaneously rotated and moved longitudinally (fig. 3).

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Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over R.A. Williams et al (Vol. 119, No. 11, November 1984) in view of Evans et al US 20020188276 as applied to claim 17 above, and further in view of Duffy et al 6,048,332.

R.A. Williams et al in view of Evans et al disclose the invention substantially as claimed. However, they fail to disclose the elongated intraluminal member is a balloon catheter. However, Duffy et al teach the elongated intraluminal member is a balloon catheter (fig. 2a, element 10 is an intraluminal member which has a balloon 20 is positioned at the distal end of the intraluminal member). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the intraluminal member of William in view of Evans with the intraluminal member is a balloon catheter as taught by Duffy in order to allow fluid that passes through the conduit out of the balloon (col. 8, lines 19-28).

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over R.A. Williams et al (Vol. 119, No. 11, November 1984) in view of Evans et al US 20020188276 as applied to claim 17 above (for example, the vein size, Vol. 119, No. 11, November 1984, page 1284) except regarding the vein has a size at the treatment site of 2-10mm. It would have been obvious to modify the vein has a size at the treatment site of 2-10mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re. Aller, 220F, 2d 454, 105 USPQ 233.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699.

The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/VN/

/Anh Tuan T. Nguyen/

Supervisory Patent Examiner, Art Unit 3731

7/18/09